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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/519,728	03/03/2000	Bruce D. Weintraub	UOFMD.002C1	6702

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EXAMINER

LAZAR WESLEY, ELIANE M

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 08/26/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/519,728

Applicant(s)
Weintraub

Examiner
Eliane Lazar-Wesley

Art Unit
1646



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jun 4, 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27-31, 39, 62, 67, and 68 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 27-31, 39, 62, 67, and 68 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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DETAILED ACTION

1. The amendment filed June 04, 2002, has been entered.

The declarations under 37CFR 1.132 have been considered and have been found persuasive.

Claims 27-31, 39, 62 and new claims 67-68 are under consideration.

New rejections apply.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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3. Claims 27-31, 39, 62 and 67-68 rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-43 and 47-57 of U.S. Patent No. 6,361,922, in view of US Patent 5,585,345.

The claims are to mutant TSH heterodimers wherein at least one amino acid substitution is at position 11-21 of the α subunit (claim 27), or at least one amino acid substitution is at position 58-69 of the β subunit (claim 28). The mutant TSH heterodimers have a greater bioactivity than the wild-type TSH. The TSH β subunit is joined via a peptide bond at its C- terminus to the N-terminus of the CTP of human chorionic gonadotropin (CG).

US Patent 6, 361,922 (Szkudlinski) teaches various TSH heterodimers mutants, wherein mutations are for example at positions 11, 13, 14, 16, 17, and 20 of the α subunit (see for example claim 1), or at positions 58, 63 and 69 (see for example claim 52). The mutants have increased activity over the wild type TSH (col.4, lines 18-25, and Figures 2A-2H for example). This patent does not teach that the TSH β subunit is joined via a peptide bond at its C- terminus to the N-terminus of the CTP of human chorionic gonadotropin (CG).

US Patent 5,585,345 (Boime) teaches CTP extended forms of glycoprotein hormones, and teaches that extended forms of β subunits wherein the CTP of human CG β subunit is appended to the C-terminus have extended biological half-lives, which makes them useful in pharmaceutical compositions (col.19, lines 5-10).

It would have been obvious for one of skill in the art at the time of the invention, and one would have been motivated to do so, to modify the teachings of '922 (Szkudlinski) regarding

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mutants having increased activity over the wild type TSH, by making CTP extended forms of the β subunit, as taught in '345 (Boime), in order to confer an extended biological half-life to the superactive form of TSH for therapeutic purposes.

Claim Rejections - 35 USC § 103

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims ^{27, 31, 39}27-31, 39, 62 and 67-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Szkudlinski, Nature Biotechnology 14:1257-1263, 14 October 1996, cited as art of record in the former Office action, in view of US Patent 5,585,345 (Boime).

Szkudlinski teaches how to engineer superactive analogues of human glycoprotein hormones. He teaches mutants of hTSH in the α subunit between positions 10 and 21, and in the β subunit, at position 69 for example, and combinations thereof, which are more potent in biological activity like cAMP stimulation, than the wild type TSH (see Table 2). He refers to studies about the engineering of long acting analogues with a prolonged plasma half-live and increased bioactivity (page 1257, col.1, end of first paragraph).

US Patent 5,585,345 (Boime) teaches CTP extended forms of glycoprotein hormones, and teaches that extended forms of β subunits wherein the CTP of human CG β subunit is appended to the C-terminus have extended biological half-lives, which makes them useful in pharmaceutical compositions (col.19, lines 5-10).

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It would have been obvious for one of skill in the art at the time of the invention, and one would have been motivated to do so, to modify the teachings of Szkludlinski regarding mutants having increased activity over the wild type TSH, by making CTP extended forms of the β subunit, as taught in '345 (Boime), in order to confer an extended biological half-life to the superactive form of TSH for therapeutic purposes.

6. No claim is allowed.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eliane Lazar-Wesley, PhD, whose telephone number is (703) 305 4059. The examiner can normally be reached on Monday-Friday from 9:30am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564.

Official papers filed by fax should be directed to (703) 308 4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

ELW

August 22, 2002

EW

